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Translation, Cultural Adaptation and Validation of the Qualiveen-30 Questionnaire in Persian for Patients with Spinal Cord Injury and Multiple Sclerosis

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Objectives: This study aimed to cross-culturally translate the Qualiveen-30 into Persian and validate it in Iranian patients with spinal cord injury (SCI) and multiple sclerosis (MS).

Methods: This was a cross-sectional prospective validation study. The translation and cross-cultural adaptation of the original questionnaire was performed in accordance with published guidelines. A total of 154 patients with SCI or MS who suffered from lower urinary symptoms for at least 6 months were asked to complete the questionnaire in the first visit to the clinic and after 3 weeks. To assess reliability, the internal consistency was assessed by Cronbach's alpha coefficient, and validity was assessed using convergent and discriminant validities.

Results: The Cronbach's alpha coefficients for the Qualiveen-30 at two assessments ranged from 0.82 to 0.95, indicating a good internal consistency for the questionnaire. There were high amounts of test-retest reliability for the Qualiveen questionnaire and each of its domains (ICC > 0.90). Also, Qualiveen and its domains had a moderate to high correlation with the International Consultation on Incontinence Questionnaire-Urinary Incontinence Short Form (ICIQ-UI SF) ($0.36 < r < 0.57$) and SF-12 MCS ($-0.51 < r < -0.11$) and SF-12 PCS ($-0.29 < r < -0.19$), indicating good convergent validity. Comparison of Qualiveen in groups of income, education and manner of voiding revealed the high discriminative power of this instrument. The hypothesized four factor structure was approved using confirmatory factor analysis (CFA).

Conclusions: In general, the Persian version of Qualiveen-30 performed is a reliable and valid measure for the evaluation of the quality of life related to lower urinary symptoms in patients with SCI or MS.

Key words quality of life, Qualiveen, reliability, translation, validity

1. INTRODUCTION

Today, the quality of life (QoL) in people with multiple sclerosis (MS) and spinal cord injury (SCI) has become an important outcome assessment for both treatment and research.[1] It is a major challenge for most healthcare systems worldwide. Although life expectancy in these neurological diseases has improved due to healthcare promotion in the last three decades,[2] there are still various factors such as Urinary Disorders (UD) which are responsible for a significant negative impact on the QoL in both SCI and MS.[3–5] The symptoms of urinary disorders in this group of patients are common and can present as a problem in the voiding or storage of urine.[6–8]

Several specific instruments have been developed and recommended to evaluate urinary symptoms in patients with lower urinary tract disorder. These instruments are Incontinence Quality of Life Instrument (I-QoL),[9] Urge Incontinence Impact Questionnaire (Urge-IIQ) and Urge Urological Distress Inventory (Urge-UDI),[10] Overactive Bladder Questionnaire (OAB-Q),[11] International Consultation on Incontinence Questionnaire-Urinary

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Incontinence Short Form (ICIQ-UI SF)[12] and Qualiveen Questionnaire.[13] Although the ICIQ-UI SF, OAB-Q, Urge-IIQ, Urge-UDI, and I-QoL questionnaires are helpful to evaluate urinary incontinence symptoms, Qualiveen is the most UD-specific Health-Related QoL (HRQoL) instrument. It not only is the most widely used instrument to evaluate UD-HRQoL in neurologic patients, but also it is the only questionnaire that addresses both storage and voiding symptoms.[14] Besides, in the 2011 review of the EAU guidelines, it has been stated that Qualiveen is the only specific tool for HRQoL for neurogenic lower urinary tract dysfunction.[15]

Although the Qualiveen questionnaire was developed for French-speaking SCI patients,[13] it was quickly translated and validated in English,[16] Spanish,[17] Portuguese,[2] German,[18] Turkish[19] and Arabic.[20] Because of the similarity of urinary problems in patients with SCI and MS, the Qualiveen questionnaire was validated and used for patients with MS, as well.[16,17,19]

In this study, the French version of Qualiveen was translated to Persian and validated to use in Persian-speaking patients with neurogenic lower urinary tract dysfunction. The aim of this study was to translate the Qualiveen-30 to Persian and to adapt it for patients who suffer from urinary symptoms and to validate it cross-culturally for Iranian patients with spinal cord injury and multiple sclerosis.

2. METHODS

2.1. Patient population

This cross-sectional study was conducted from November 2011 to May 2012. The study included 154 outpatients with SCI or MS (80 SCI and 74 MS) who were suffering from lower urinary tract symptoms for at least 6 months. The participants were selected from two medical centers that were affiliated with Tehran University of Medical Sciences, the Spinal Cord Injury Clinic at Imam Khomeini Hospital (BASIR) and the Multiple Sclerosis Clinic at Sina Hospital (MSRC). These selected centers are two major referral centers for SCI and MS patients in Iran.

The inclusion criteria were age older than 18 years, ability to read and speak in Persian, lower urinary tract symptoms for at least 6 months, suffering from MS based on the Poser criteria or complete or incomplete SCI according to their medical records, no evidence of acute urinary infection, no symptoms or signs of cognitive impairment, and consent to participate in the study. Patients with cognitive impairment and pregnant women were excluded. The study obtained the necessary ethical approval from the Ethics Committee of Tehran University of Medical Sciences and all patients signed up an informed consent form before collecting data.

2.2. Instruments

2.2.1. Qualiveen-30

The Qualiveen is a 30 item questionnaire that focuses on four aspects of patients' lives including bother with limitations (nine items), frequency of limitations (eight items), fears (eight items), and feelings (five items). The Qualiveen is a Likert-type questionnaire in which each question has five options to be answered. The option 0 indicates that urinary problems have no effect on the quality of life, while option 4 indicates a great adverse effect on the quality of life of the patients.[13] The mean score of the items in each domain indicates the score for that domain and the overall score of Qualiveen is the mean of the four domains.

2.2.2. ICIQ-UI SF

The ICIQ-UI SF is an instrument that was developed to evaluate the burden of urinary incontinency in patients' daily life. The ICIQ-UI SF assesses the symptoms that influence the QoL. It has four questions that evaluate frequency, severity, effect of incontinence on patients' QoL and usual urinary leakage situations.[12] The ICIQ-UI SF questionnaire used in this study was its Persian version, which had been translated and validated in another study.[21]

2.2.3. SF-12 Questionnaire

The SF-12 questionnaire is a short form of the SF-36 questionnaire. The questionnaire has 12 items to examine two aspects, i.e. physical and psychological aspects, of QoL. These aspects were summarized into two summary scores: the physical component summary (PCS-12) and the mental component summary (MCS). The Persian version of SF-12 has already been validated and adapted to Persian-speaking population in another study.[22]

2.3. The Qualiveen-30 translation procedure

Multi-stage forward-backward-translation procedure, which is suggested by Beaton et al.,[23,24] was followed to translate the French version of the Qualiveen-30 questionnaire and obtain the final Persian version of the questionnaire. Two native Persian-speaking urologists who were expert in French translated the questionnaire independently into Persian. Afterward, a professional interpreter reconciled the translation disparities. Once the Persian version of the Qualiveen-30 was developed, it was back-translated into French by a native French speaker fluent in Persian. The purpose of back-translation was to ensure the content of the translation remained consistent with the original version of the questionnaire. Review of the back-translated version revealed four minor discrepancies that were corrected in the next draft of the Persian Qualiveen.

In addition, a comaprsion was made between the back-translated and original French version of the questionnaire. After a careful review and cultural adaptation, few changes were made and the provisional draft of the Persian version of the Qualiveen questionnaire was provided.

Testing of the provisional draft was performed in a pilot study with six SCI and five MS patients who suffered from lower urinary tract symptoms to provide feedback regarding the final Persian version of the Qualiveen in order to

fine-tune the wording of each item. There were two purposes for the fine-tuning process. The first was to make sure the questionnaire measured what the researchers intend to examine by the questionnaire and the second purpose was to make sure that the patients could understand and complete the Persian version of the questionnaire easily. Most patients correctly understood the questionnaire items and their general comments on the difficulty of filling out the questionnaire or understanding each item were asked. After a consensus by all researchers, the final version was developed and used in this study.

2.4. Procedures

The participants were asked to complete the demographic form, the Persian version of Qualiveen, the Persian version of SF-12[25] and the Persian version of ICIQ-UI SF[21] in the first visit after obtaining an informed consent. The Persian version of Qualiveen with an empty stamped envelope was posted to the subjects after 3 weeks. They were asked to complete and return the questionnaire to assess test-retest reliability. Demographic and some clinical characteristic data were collected through a self report form including age, gender, education, income, marital status and manner of voiding.

2.5. Statistical analysis

Statistical reliability methods were performed for the overall score of Persian Qualiveen and its four domains. Intra-class correlation coefficient (ICC) was used to evaluate test-retest reliability. In addition, Cronbach's alpha was calculated to assess internal consistency.

Construct validity was assessed by examining the convergent validity and discriminant validity. For convergent validity, it was hypothesized that the Persian Qualiveen and its domains were significantly correlated with ICIQ-UI SF and SF-12 PCS and SF-12 MCS. Pearson's correlation coefficient was used for calculating the correlation. For discriminant validity, it was hypothesized that the Persian Qualiveen and its domains could be significantly different in the levels of variables such as the manner of voiding, age, education and income status. Effect sizes were calculated using Cohen's statistic (difference in means divided by the standard deviation of the difference) to compare the scores of the Persian version in the categories of ICIQ-UI and SF-12 PCS and SF-12 MCS scores (<40 vs. ≥ 40). The results of the Cohen's statistic were interpreted as small, moderate, or large based on values of 0.2, 0.5, and 0.8, respectively.[26] Ceiling and floor effects of the Persian version and its domains were measured at baseline and follow-up. The ceiling and floor effect less than 15% was considered an acceptable standard measurement.[27]

Analysis of variance (ANOVA) or independent-samples *t*-test was used to investigate the significant differences between sample means in this study. The Tukey multiple comparison method was used for post-hoc analysis. The normality of the variables was checked by Chapiro-Wilk test and homogeneity of the variance in the groups was tested by Levene statistic. SPSS software (version 18, IBM Corporation, New York, NY, USA) was used for data analysis. In this study, a P-value <0.05 was considered statistically significant.

To assess factor structure of the Persian version of the Qualiveen, confirmatory factor analysis was conducted. The four factors were restriction, bother with limitations, frequency of limitations, fears, and feelings. The confirmatory factor analysis (CFA) was estimated using weighted least squares (WLS). A single-step model (CFA) was conducted on the entire sample in an attempt to test the hypothesized structural four-factor structure of the Qualiveen. Several goodness-of-fit indices were used to assess the fit of the hypothesized model to the current sample. The root-mean-square error of approximation (RMSEA), χ^2 statistic, comparative fit index (CFI) and non-normed fit index (NNFI) were examined. A non-significant χ^2 statistic indicates overall model fit of the data. However, χ^2 statistic is sensitive to sample size. Therefore, it should be interpreted in conjunction with other fit indices. A RMSEA value less than or equal to .08 is considered acceptable, while values equal or higher than 0.90 for the CFI, NNFI are considered acceptable.[28,29]

3. RESULTS

Table 1 shows the demographic and clinical characteristics of the participants. The mean age of the patients was 35.3 years and most of the patients were between 35 and 44 years of age (44.2%). Sixty-five patients (42.2%) were female. Ninety-eight patients (64.1%) completed high school diploma or had higher education. The majority of the patients had moderate income (67.5%) and were married (66.7%). Thirty-four percent of the patients had normal voiding with some urinary problems. The distributions of Qualiveen, ICIQ-UI SF and SF12 are depicted on the box plots in Fig. 1.

3.1. Internal consistency

Cronbach's alpha coefficient was used to evaluate the internal consistency of Persian Qualiveen at baseline and follow-up. Cronbach's alpha for the overall score of Persian Qualiveen was 0.95 at two measurements. It was 0.89 for the ''*bother with limitations*''; 0.93 for the ''*frequency of limitations*''; 0.89 for the ''*fears*''; and 0.85 for the ''*feelings*'' domains at baseline. Approximately the same high values of internal consistency were obtained at follow up (Table 2).

3.2. Test-retest reliability

Intra-class correlation coefficient was used to calculate the stability of the questionnaire. There was a high test-retest reliability for the Qualiveen questionnaire and its each domains. The ICC value was 0.97 for the total Qualiveen score, 0.96 for *bothers*, 0.96 for *frequency of limitations*, 0.97 for *fears*, and 0.94 for *feelings* domain, which showed a high reliability (Table 2).

3.3. Convergent validity

As hypothesized, there were positive correlations between Qualiveen and ICIQ-UI SF ($r = 0.57$) and also

TABLE 1. Demographic and clinical characteristics of patients

Variables	$n = 154$
Gender	
Male	89 (57.8)
Female	65 (42.2)
Age (year, mean ± SD)	35.33 ± 9.8
Younger than 25	18 (11.7)
25–34	68 (44.2)
35–44	44 (28.6)
45 and higher	24 (15.6)
Education	
Illiterate and primary school	21 (13.7)
Middle and high school	34 (22.2)
High school diploma and college	53 (34.6)
Higher education	45 (29.4)
Income	
Good	26 (17.2)
Moderate	102 (67.5)
Poor	23 (15.2)
Marital status	
Single	51 (33.3)
Married	102 (66.7)
Manner of voiding	
Normal voiding	51 (34.0)
Indwelling catheter	23 (15.3)
Intermittent catheter	30 (20.0)
Condom sheath and napkin	24 (16.0)
Other (Tapping, massage, abdominal pressure, etc.)	22 (14.7)

Values are given as *n* (%) or mean ± SD.

as expected, higher values of Qualiveen were linearly associated with lower values of SF-12 MCS and SF-12 PCS, indicating that physical health and mental health, as general quality of life, was correlated significantly with urinary disorder specific quality of life $r = -0.29$ and $r = -0.32$, respectively. The correlation between the overall score of Qualiveen, domains of Qualiveen, ICIQ-UI SF and SF-12 MCS and SF-12 PCS is shown in Table 3.

TABLE 2. Descriptive statistics and reliability scale for the Qualiveen questionnaire

		n	Floor *n* (%)	Ceiling *n* (%)	Cronbach's alpha	ICC
Qualiveen	Baseline	154	0 (0)	0 (0)	0.95	0.97
	Follow-up	145	0 (0)	0 (0)	0.95	
Bother with limitations	Baseline	154	1 (0.6)	2 (1.3)	0.89	0.96
	Follow-up	145	1 (0.7)	2 (1.4)	0.89	
Frequency of limitations	Baseline	153	2 (1.3)	1 (0.7)	0.93	0.96
	Follow-up	145	1 (0.7)	1 (0.7)	0.82	
Fears	Baseline	153	1 (0.7)	4 (2.6)	0.89	0.97
	Follow-up	144	1 (0.7)	5 (3.5)	0.91	
Feelings	Baseline	153	16 (10.5)	3 (2.0)	0.85	0.94
	Follow-up	142	12 (8.5)	4 (2.8)	0.88	

3.4. Discriminant validity

The overall Qualiveen scores and its each domain for different grouping variables are shown in Table 4. As expected, patients with higher levels of education had significantly better urinary disorder specific quality of life ($P < 0.001$) and also patients with good income had better urinary quality of life compared to low and moderate income patients ($P < 0.05$). As hypothesized, the manner of voiding has significant effect on patient's quality of life. Participants with normal voiding had significantly lower values for Qualiveen and all its domains ($P < 0.05$).

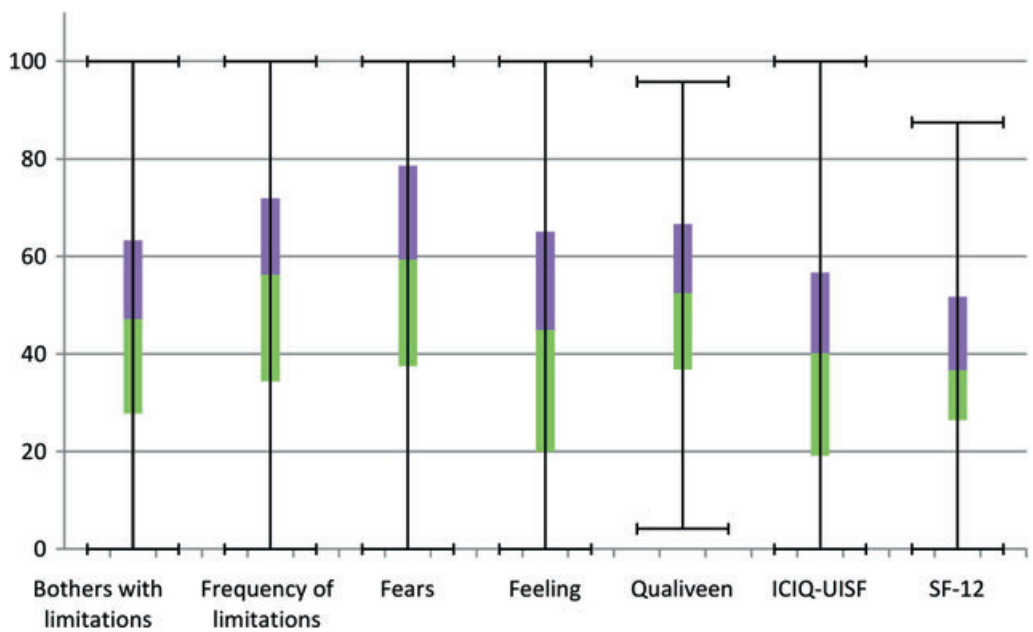

Fig. 1 Box plots distribution for Qualiveen, International Consultation on Incontinence Questionnaire-Urinary Incontinence Short Form (ICIQ-UI SF) and SF-12.

3.5. Effect size

Effect size indices, unlike significant tests, are independent of the sample size. There are different methods to achieve them. Standardized differences between two means were used to calculate the effect size in this study. Cohen's d (effect size) can also be interpreted in terms of non-overlap measures in comparison between two groups.[26] For example, a non-overlap of 0% (equals with ES of 0.0) indicates that distribution scores for two groups are completely overlapped. Results from the known group comparisons between subgroups of patients formed on the basis of the ICIQ-UI SF and SF-12 PCS and SF-12 MCS are summarized in Table 5. The non-overlap measure for overall Qualiveen score based on ICIQ-UI SF and SF-12 were 65.3 and 27.4%, respectively.

TABLE 3. Correlation between the Qualiveen questionnaire and its domains with SF-12 and International Consultation on Incontinence Questionnaire-Urinary Incontinence Short Form (ICIQ-UI SF)

	1	2	3	4	5	6	7	8
1. Overall score of Qualiveen	1	0.85	0.87	0.82	0.76	−0.29	−0.32	0.57
2. Bother with limitations	–	1	0.71	0.57	0.46	−0.26	−0.27	0.55
3. Frequency of limitations	–	–	1	0.56	0.59	−0.27	−0.48	0.52
4. Fears	–	–	–	1	0.59	−0.19	−0.51	0.42
5. Feelings	–	–	–	–	1	−0.25	−0.29	0.36
6. SF-12 PCS	–	–	–	–	–	1	−0.11	−0.17
7. SF-12 MCS	–	–	–	–	–	–	1	−0.25
8. ICIQ-UI SF	–	–	–	–	–	–	–	1

All Pearson's (r) coefficient were significant ($P < 0.05$) except correlation between SF-12 & ICIQ-UISF.

3.6. Factor structure

The hypothesized four factor structure with 30 items was tested using the full sample of participants. The results indicated that the fit model was acceptable ($\chi^2 = 815.27$, df = 399, RMSEA = 0.078, CFI = 0.95, NNFI = 0.94).

TABLE 4. Mean and standard deviation of the Qualiveen in levels of other variables

	Qualiveen Mean ± SD	*P*-value	Bother with limitations Mean ± SD	*P*-value	Frequency of limitations Mean ± SD	*P*-value	Fears Mean ± SD	*P*-value	Feelings Mean ± SD	*P*-value
Gender										
Male	56 ± 18.8	< 0.001	50.5 ± 21.1	0.029	59.2 ± 22.5	< 0.001	63 ± 24	0.002	49.8 ± 28.7	< 0.001
Female	42.2 ± 22.4		42.3 ± 24.8		43.3 ± 27.4		47.8 ± 29.2		32.1 ± 23.1	
Age										
Younger than 25	45.5 ± 24.8	0.579	42 ± 22	0.192	50.6 ± 33.3	0.990	50.6 ± 30.5	0.616	38.5 ± 26.6	0.972
25–35	51.7 ± 21.6		50.8 ± 24.1		52.0 ± 25.7		68.6 ± 27.9		42.9 ± 28.7	
35–45	47.6 ± 18.1		42.5 ± 20.3		50.4 ± 24.1		54.5 ± 24.4		42.1 ± 26.5	
45 and higher	47.5 ± 24.6		42.2 ± 25.1		52.2 ± 26.4		51.7 ± 28.6		42.0 ± 32.1	
Education										
Illiterate and primary school	55.9 ± 20.7	0.001	55.2 ± 23.0	0.011	57.1 ± 24.1	0.006	62.5 ± 23.7	0.004	44.8 ± 27.8	0.015
Middle and high school	55.3 ± 18.9		46.4 ± 22.5		57.2 ± 23.2		66.2 ± 22.7		51.8 ± 27.7	
High school diploma and college	52.7 ± 19.8		51.0 ± 21.4		56.9 ± 24.9		57.7 ± 27.4		43.1 ± 25.8	
Higher education	39.7 ± 21.9		38.3 ± 22.7		41.1 ± 26.5		44.5 ± 28.0		32.2 ± 27	
Income										
Good	39.7 ± 19.4	0.027	41.2 ± 21.0	0.363	44.5 ± 23.5	0.116	38.4 ± 26.1	< 0.001	29.2 ± 22.9	0.007
Moderate	52.2 ± 21.8		47.7 ± 23.8		53.8 ± 26.7		60.6 ± 26.5		45.5 ± 28.1	
Poor	50.6 ± 19.0		49.5 ± 20.9		52.6 ± 23.3		56.6 ± 25.1		40.9 ± 27.5	
Marital status										
Single	53.6 ± 20.9	0.127	47.6 ± 22.5	0.761	56.2 ± 25.6	0.189	62.6 ± 26.3	0.046	47.5 ± 27.2	0.078
Married	48.0 ± 21.3		46.4 ± 23.2		50.4 ± 25.7		53.2 ± 27.2		39.3 ± 27.4	
Manner of voiding										
Normal voiding	34.88 ± 18.39	< 0.001	36.24 ± 21.91	< 0.001	33.25 ± 22.74	< 0.001	39.63 ± 24.42	< 0.001	29.12 ± 23.53	0.001
Indwelling catheter	53.89 ± 19.64		48.55 ± 20.51		58.02 ± 22.71		61.36 ± 26.68		46.52 ± 26.77	
Intermittent catheter	62.67 ± 14.87		58.55 ± 19.44		66.67 ± 17.55		69.18 ± 19.98		53.50 ± 26.40	
Condom sheath and napkin	59.74 ± 21.60		53.02 ± 25.72		69.02 ± 21.11		67.37 ± 29.27		47.61 ± 31.37	
Other (Tapping, massage, abdominal pressure, etc.)	54.26 ± 17.78		49.54 ± 20.18		54.40 ± 23.18		62.49 ± 21.31		48.18 ± 27.93	

TABLE 5. Comparison of scores of overall Qualiveen and its domains with the effect size measures based on International Consultation on Incontinence Questionnaire-Urinary Incontinence Short Form (ICIQ-UI SF) and SF-12

	ICIQ-UI SF				SF-12 PCS				SF-12 MCS			
	<40 $n=76$ Mean ± SD	≥ 40 $n=76$ Mean ± SD	Effect size	Percent of non-overlap (%)	<40 $n=87$ Mean ± SD	≥ 40 $n=64$ Mean ± SD	Effect size	Percent of non-overlap (%)	<40 $n=81$ Mean ± SD	≥ 40 $n=70$ Mean ± SD	Effect size	Percent of non-overlap (%)
Qualiveen†‡	38.5 ± 21.9	61.4 ± 13.4	1.30	65.3	54.1 ± 19.2	45.5 ± 23.4	0.40	27.4	52.1 ± 18.6	47.5 ± 20.5	0.23	27.4
Bother with limitations†‡	36.3 ± 20.9	57.4 ± 20.1	1.03	55.4	51.1 ± 21	42.6 ± 24.5	0.37	27.4	53.0 ± 20.2	40.6 ± 25.5	0.54	27.4
Frequency of limitations†‡	40.0 ± 26.6	64.6 ± 17.8	1.09	58.9	56.4 ± 24.6	47.8 ± 26.7	0.34	21.3	52.1 ± 25.1	49.4 ± 24.2	0.11	21.3
Fears†	43.5 ± 27.0	69.3 ± 20.7	1.07	58.9	60.2 ± 25.0	52.0 ± 29.7	0.30	21.3	59.1 ± 25.5	50.7 ± 29.4	0.31	21.3
Feelings†	33.0 ± 27.7	51.5 ± 25.0	0.70	43.0	46.0 ± 26.1	37.9 ± 29.5	0.30	21.3	41.0 ± 25.7	38.8 ± 28.6	0.08	21.3

†Statistically significant for ICIQ-UI SF ($P < 0.05$ lowest through 40 vs. ≥40). ‡Statistically significant for SF-12 ($P < 0.05$ lowest through 40 vs. ≥40).

4. DISCUSSION

Although many non-specific questionnaires have been developed to evaluate urinary symptoms in neurological patients, none can solely evaluate the urinary symptoms-related QoL in this population. The Qualiveen is a specific questionnaire that evaluates all aspects of special needs and complaints of patients with neurological disorders. The Qualiveen was translated and validated in this study because there was no available questionnaire to assess the urinary symptoms-related QoL for Persian-speaking neurological patients.

The Quliveen was originally designed and used in western countries[13] but it is not extensively used in eastern cultures.[19,20] In particular, people from Middle Eastern countries have diverse beliefs regarding urinary problems, which root from their religious perspectives. Due to cultural and linguistic differences, a rigorous translation procedure is essential to develop a health-related QoL questionnaire that is well applicable in a population with a different culture, beliefs, religion and language. In this study, a multi-stage forward-backward-translation procedure, suggested by Beaton et al.,[23,24] was used to guide authors through the process of developing a normalized sequence for the same questionnaire for different populations. Participants did not report any major problems in understanding the Persian version of Qualiveen-30.

The reliabilty and validaty study revealed that the Persian version of Qualiveen had a very good internal consistency with Cronbach's alpha coefficient greater than 0.80 for the Qualiveen and all of its domains. In this study, ICCs for test-retest reliability were greater than 0.90, indicating an excellent test-retest reliability for the Persian version of Qualiveen-30, which is higher than all other published studies.[2,3,13,17–20] Convergent validity was measured as the correlation of Qualiveen with ICIQ-UI SF. A significant correlation was observed between the Persian version of Qualiveen-30 and ICIQ-UI SF indicating a good convergent validity. Despite high correlations between ICIQ-UI SF and Qualiveen-30, relatively weak correlations were found between both SF-12 MCS and SF-12 PCS. Maybe, the reason for this is that the SF-12 is a generic tool and not a disease-specific tool to capture clinical change.

Comparison of Quliveen in categories of the variables, income, education, and manner of voiding showed the high discriminative power of this instrument, similar to the French and English versions.[13,16]

There is no doubt about the necessity of having a reliable questionnaire in Persian because of the high prevalence of SCI, MS and other neurological urinary disorders in Iran. SCI has a very high prevalence in Iran due to the high rate of motor vehicle accidents.[30] A study reported a prevalence of 4.4 in 10 000 for SCI in Tehran (the capital of Iran). In addition, the prevalence of MS in Iran has been reported from 50.6 to 73.7 in 100 000 in published studies,[31,32] summing a total number with a range of 38 500–56 000 . In addition, Persian is the official language of two other countries, Afghanistan

and Tajikistan, with populations of 34.0 and 7.2 million, respectively, that can be a target for the Persian version of Quliveen.[33] These countries are culturally very similar to Iran. There are slight language differences between Persian-speaking countries, but people in these countries understand each other very easily. In the translation procedure, we tried to use the words that are common and understandable in all Persian-speaking countries. Therefore, we believe that the Persian version of the Quliveen is applicable in all Persian-speaking countries. Future studies should assess the discriminant validity of the Persian version of the Qualiveen between healthy people without neurogenic bladder and patients with neurogenic bladders.

The Qualiveen is a comprehensive questionnaire for QoL evaluation in patients with urinary dysfunction, which proved useful for SCI and MS patients.The results showed that the Qualiveen was validated for both SCI and MS without demonstrating any significant difference between the two groups. The only inconvenience of the instrument is its length, but its completeness enables in-depth evaluation of the patients' perception, making the Qualiveen an excellent instrument for research trials.

5. CONCLUSION

In conclusion, in this study, the process of translation, cross-cultural adaptation and validation of the French Qualiveen questionnaire to Persian was done successfully. It is recommended that health centers and clinics use the Persian version of the Qualiveen in order to assess urinary symptoms-related QoL in patients with SCI or MS who suffer from urinary incontinence due to the neurogenic bladder.

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Disclosure

The authors declare no conflict of interests.

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